K012274

FEB 0 5 2002

SECTION E - 510(k) SUMMARY

Submitter's Name and Address:

Medtronic Physio-Control Corp.
11811 Willows Road Northeast
P.O. Box 97006
Redmond, WA 98073

Contact Person:

Sherri L. Pocock
(425) 867-4332

Date Summary Prepared:

June 12, 2001

Device:

Medtronic Physio-Control LIFEPAK® 20 Defibrillator/Monitor/ Pacemaker

Classification:

Low-Energy DC - Defibrillators: Class II (21 CFR 870.5300)

Automatic External Defibrillators have been considered Class III devices by FDA.

Cardiac Monitors (including Cardiotachometers and Rate Alarms): Class II (21 CFR 870.2300)

External Transcutaneous Cardiac Pacemakers (Noninvasive): Class II (870.5550)

Oximeters: Class II (21 CFR 870.2700)

Description:

The LIFEPAK 20 device is a defibrillator/monitor primarily intended for the hospital and clinic setting. It is easy to use, portable, easy to maintain, and fits comfortably on a gurney during transport. It has a built in AC power supply and backup NiMH battery. It uses a biphasic waveform with an energy range from 2 – 360 Joules.

Features and options include: external noninvasive pacemaker; pulse oximeter; 3-, 6-, and 7-lead ECG; defibrillation paddles; ability to use all disposable electrodes or paddles currently used with the LIFEPAK 12 defibrillator/monitor/pacemaker; internal paddles capability; 50 mm printer; automated external defibrillator mode; built in AC power with NiMH battery backup; digital remote synchronization to bedside monitor; and an infrared and serial ports for data download.

Substantial Equivalence:

The features and functions of the LIFEPAK 20 defibrillator/monitor are substantially equivalent to those of the Medtronic Physio-Control LIFEPAK 9P defibrillator/monitor: 510(k) no. K902288, cleared 5/21/90, and the LIFEPAK 12 defibrillator/monitor: 510(k) nos. K973486, cleared 1/9/98; and K991910, cleared 9/3/99.

Indications for Use:

Defibrillation is a means of terminating certain potentially fatal arrhythmias, such as ventricular fibrillation and symptomatic ventricular tachycardia. A direct current defibrillator applies a brief, intense pulse of electricity to the heart muscle. Delivery of this energy in the synchronized mode is a method for treating atrial fibrillation, atrial flutter, paroxysmal supraventricular tachycardia, and, in relatively stable patients, ventricular tachycardia.

The biphasic waveform has only been clinically studied on adults; it has not been studied on pediatric patients.

The Automated External Defibrillation mode is for use on patients in cardiopulmonary arrest. It is not intended for use on patients less than 8 years old.

Noninvasive pacing is used as a means of treating symptomatic bradycardia and asystole.

3-lead (3 wire), 6-lead (4 wire), and 7-lead (5 wire) ECG monitoring allows for identification or interpretation of cardiac rhythms or dysrhythmias and calculation of heart rate.

Pulse Oximetry is used to check the saturation of oxygen in arterial blood (SpO_2). It is indicated for use in any patient who is at risk of developing hypoxemia.

Summary of Performance Information:

The 510(k) includes documentation related to the compliance of the LIFEPAK 20 device with AAMI, IEC, and ISO defibrillator, monitor, and pulse oximeter standards.

The information in this 510(k) demonstrates that the LIFEPAK 20 defibrillator/monitor is substantially equivalent to the predicate devices with respect to safety, effectiveness, and performance.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 0 5 2002

Ms. Sherri L. Pocock
Regulatory Advisor
Medtronic Physio-Control Corporation
11811 Willows Road NE
P.O. Box 97006
Redmond, WA 98073-9706

Re: K012274
Trade Name: LifePak® 20 Defibrillator/Monitor
Regulation Number: 21 CFR 870.1025, 870.5300, 870.5550
Regulation Name: Arrhythmia Detector, Defibrillator, External Transcutaneous Cardiac Pacemaker
Regulatory Class: Class III (three)
Product Code: MKJ, LDD, DRO
Dated: November 6, 2001
Received: November 7, 2001

Dear Ms. Pocock:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for

Bram D. Zuckerman, M.D.
Acting Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Ver/ 3 - 4/24/96

Applicant: Medtronic Physio-Control Corp.

510(k) Number (if known): 510(k) Number Not yet assigned

Device Name: LIFEPAK 20 Defibrillator

Indications For Use:

Defibrillation is indicated for the termination of certain potentially fatal arrhythmias, such as ventricular fibrillation and symptomatic ventricular tachycardia. Delivery of this energy in the synchronized mode is a method for treating atrial fibrillation, atrial flutter, paroxysmal supraventricular tachycardia, and, in relatively stable patients, ventricular tachycardia.

The biphasic waveform has only been clinically studied on adults; it has not been studied on pediatric patients.

The AED mode is to be used only on patients in cardiopulmonary arrest. The patient must be unconscious, pulseless, and not breathing spontaneously before using the defibrillator to analyze the patient's ECG rhythm.

In AED mode, the LIFEPAK 20 defibrillator/monitor is not intended for use on pediatric patients less than eight years old.

Noninvasive pacing as a therapy is indicated for patients with symptomatic bradycardia or asystole.

Pulse Oximetry is indicated for use in any patient who is at risk of developing hypoxemia.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Division of Cardiovascular & Respiratory Devices
510(k) Number K012274

Prescription Use ✓
(Per 21 CFR 801.109)